IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE ORPHAN THERAPIES LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	
	)	C.A. No. 15-1102 (GMS)
v.	)	CONSOLIDATED
FRESENIUS KABI USA, LLC,	)	
Defendant.	)	

PLAINTIFFS' ANSWER AND AFFIRMATIVE DEFENSES TO DEFENDANT'S SECOND AMENDED COUNTERCLAIMS

Shire Orphan Therapies LLC and Sanofi-Aventis Deutschland GmbH (collectively "Plaintiffs" or "Counterclaim-Defendants"), by their undersigned attorneys, hereby submit their Answer and Affirmative Defenses to the Second Amended Counterclaims ("Counterclaims") of Fresenius Kabi USA, LLC ("Fresenius" or "Defendant") as follows:

PARTIES

1. Fresenius is a limited-liability company organized under the laws of the State of Delaware with its principal place of business located at Three Corporate Drive, Lake Zurich, Illinois 60047.

ANSWER: Admitted, upon information and belief.

2. On information and belief, Shire Orphan Therapies LLC purports to be a limited-liability company organized and existing under the laws of Delaware with its principal place of business located at 300 Shire Way, Lexington, Massachusetts 02421.

ANSWER: Admitted.

3. On information and belief, Sanofi-Aventis Deutschland GmbH purports to be a company organized and existing under the laws of Germany with its principal place of business located at Brüningstrasse 50, D-65926, Frankfurt am Main, Germany.

ANSWER: Admitted.

JURISDICTION AND VENUE

4. This counterclaim for a declaratory judgment arises under the patent laws of the United States, 35 U.S.C. §100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: The allegations of Paragraph 4 set forth legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that Fresenius's Counterclaims purport to arise under the patent laws of the United States and the Declaratory Judgment Act. Plaintiffs deny that Fresenius's Counterclaims for a declaratory judgment should be granted. Plaintiffs deny any remaining allegations in Paragraph 4.

5. Plaintiffs have filed a Complaint seeking, *inter alia*, a judgment that Fresenius has infringed the '333 patent based on the submission of ANDA No. 208317 to the FDA, and that the manufacture, use, offer for sale, and/or sale in the United States, and/or the importation in to the United States, of the product described in ANDA No. 208317 would infringe the '333 patent. Accordingly, an immediate and justiciable controversy exists between Fresenius and Plaintiffs, regarding whether Fresenius has infringed any valid claim of the '333 patent based on the submission of ANDA No. 208317 to FDA, and regarding whether the manufacture, use, offer for sale, and/or sale in the United States, and/or the importation into the United States, of the product described in ANDA No. 208317 would infringe the '333 patent.

ANSWER: Plaintiffs admit that they have filed a Complaint seeking a judgment that Defendant has infringed the '333 patent and that a controversy exists between Plaintiffs and Defendant as to Defendant's infringement of and the validity of the '333 patent. Except as expressly admitted, Plaintiffs deny the remaining allegations in Paragraph 5.

6. Subject matter jurisdiction in this Court is proper under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

ANSWER: The allegations of Paragraph 6 set forth legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338. Except as expressly admitted, Plaintiffs deny the remaining allegations in Paragraph 6.

7. The Court has personal jurisdiction over Plaintiffs because Plaintiffs purposely availed themselves of this forum by filing their Complaint against Fresenius based on its submission of ANDA No. 208317.

ANSWER: The allegations of Paragraph 7 set forth legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that they do not contest personal jurisdiction for the purpose of this case only. Except as expressly admitted, Plaintiffs deny the remaining allegations in Paragraph 7.

8. Venue as to these Counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

ANSWER: The allegations of Paragraph 8 set forth legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that they do not contest venue for the purpose of this case only. Except as expressly admitted, Plaintiffs deny the remaining allegations in Paragraph 8.

PROSECUTION HISTORY AND FACTUAL BACKGROUND

9. On information and belief, the ’333 patent, entitled “Peptide Having Bradykinin Antagonist Action,” was issued by the United States Patent and Trademark Office (“USPTO”) on July 15, 1997, and as a result of continuation or continuation-in-part applications dating back to June 30, 1989.

ANSWER: Plaintiffs admit the allegations of Paragraph 9, except Plaintiffs deny Paragraph 9 to the extent it alleges that the title of the ’333 patent is “Peptide Having Bradykinin Antagonist Action.” Further answering, the title of the ’333 patent is “Peptides Having Bradykinin Antagonist Action.”

10. Specifically, the ’333 patent is based on USSN 08/487,442 (“ ’442 application”) filed June 7, 1995, as a continuation of USSN 08/236,018 (“ ’018 application”), now abandoned filed May 2, 1994. The ’018 application is a continuation of USSN 08/012,849 (“ ’849 application”), now abandoned, filed February 3, 1993, which in turn is a continuation-in-part of each of USSN 07/982,052 (“ ’052 application”), USSN 07/969,523 (“ ’523 application”), and USSN 07/837,090 (“ ’090 application”).

ANSWER: Admitted.

11. The ’052 application, now abandoned, filed November 25, 1992, is a continuation of USSN 07/746,149 (“ ’149 application”), now abandoned, filed August 14, 1991, which is a continuation-in-part of USSN 07/374,162 (“ ’162 application”), now abandoned, filed June 30, 1989, which claims priority to the following three German applications: DE P 39 18 225.8, filed June 3, 1989; DE P 39 16 291.5, filed May 19, 1989, and DE P 38 39 581.9, filed November 24, 1988.

ANSWER: Admitted.

12. The ’523 application, now abandoned, filed October 30, 1992, is a continuation of USSN 07/841,766 (“ ’766 application”), now abandoned, filed March 2, 1992, which is a continuation of USSN 07/690,297 (“ ’297 application”), now abandoned, filed April 24, 1991, which is a continuation-in-part of USSN 07/565,270 (“ ’270 application”), now abandoned, filed August 10, 1990 and which claims priority to German application DE P 40 13 270.6, filed April 26, 1990.

ANSWER: Plaintiffs admit the allegations of Paragraph 12, except Plaintiffs deny Paragraph 12 to the extent it alleges that the ’270 application claims priority to German application DE P 40 13 270.6. Further answering, Plaintiffs state that the ’297 application claims priority to German application DE 40 13 270.6, filed April 26, 1990.

13. The ’090 application, now abandoned, filed February 18, 1992, is a continuation-in-part of the ’149 application, now abandoned, filed August 14, 1991, and a continuation-in-part of the ’270 application, now abandoned, filed August 10, 1990, which is a continuation-in-part of the ’162 application, now abandoned, filed June 30, 1989, and claims priority to German application DE P 39 26 822.5, filed August 14, 1989.

ANSWER: Plaintiffs admit the allegations of Paragraph 13, except that Plaintiffs deny Paragraph 13 to the extent it alleges that the ’090 application claims priority to German application DE P 39 26 822.5, filed August 14, 1989. Further answering, Plaintiffs state that the ’270 application claims priority to German application DE P 39 26 822.5, filed August 14, 1989.

14. The ’162 application is the earliest U.S. patent application of which the ’333 patent claims the benefit. During prosecution of the ’162 application, the Plaintiffs stopped substantively responding to office actions, and began a pattern of only filing extensions of time and continuation and continuation-in-part applications containing the same or very similar claims as the rejected claims of the parent application. In particular, over a four-year period from May 31, 1991 to May 30, 1995, the Plaintiffs failed to file any substantive claim amendments or traverse any USPTO rejections. Instead of responding to any of the nine office actions, the Plaintiffs filed seven continuation or continuation-in-part applications. On the eve of the implementation of the GATT patent term legislation, on information and belief, Plaintiffs

conducted an examiner interview on May 30, 1995, to discuss outstanding rejections. The Plaintiffs' responses to office actions after the May 30, 1995 interview often included a petition for three-month extension of time.

ANSWER: Plaintiffs admit that the '162 application is the earliest U.S. patent application of which the '333 patent claims the benefit. Plaintiffs deny the remaining allegations of Paragraph 14.

15. On information and belief, the Plaintiffs' failure to advance prosecution was a deliberate strategy to manipulate the U.S. patent system to delay issuance of any patent.

ANSWER: Denied.

16. On information and belief, the Plaintiffs failed to advance prosecution of the subject matter claimed in the '333 patent in order to delay issuance of claims encompassing icatibant for as long as possible so as to obtain an extension of their monopoly of the claimed subject matter. For example, the cover of the May 31, 1991, Final Office Action in the '162 application prosecution indicated that claim 13, directed to icatibant, was allowed. Rather than allow the application to receive a patent grant, the Plaintiffs filed a continuation-in-part application.

ANSWER: Denied.

17. The Plaintiffs' unreasonable and unexplained delay constitutes misuse of the statutory patent system under a totality of the circumstances. On information and belief, by failing to advance prosecution and filing successive continuation applications, the Plaintiffs' delay unjustifiably extended their monopoly over FIRAZYR®. By stalling prosecution via the filing of a plurality of continuations with no substantive amendments to advance prosecution, Plaintiffs obtained a patent which originally was not set to expire until July 15, 2014, 25 years after the first application in the chain was filed. Moreover, the '333 patent issued before the August 25, 2011 FDA approval date of FIRAZYR®, and the '333 patent had been awarded a five (5) year patent term extension ("PTE") under 35 U.S.C. § 156. This award of PTE extended their monopoly by an additional 5 years, to a date that is more than 30 years after the filing date of the first U.S. application.

ANSWER: Plaintiffs admit that FIRAZYR® was approved by FDA on August 25, 2011. Plaintiffs further admit that the '333 patent was awarded a five year patent term extension under 35 U.S.C. § 156. Plaintiffs deny the remaining allegations of Paragraph 17.

18. On information and belief, during the Plaintiffs' period of delay, at least one company, Nova Pharmaceutical Corporation, invested in the subject matter of the claims of the '333 patent. Specifically, Kyle *et al., Design and Conformational Analysis of Several Highly Potent Bradykinin Receptor Antagonists*, J MED CHEM. 34:1230-33 (1991) ("Kyle") discloses

independent invention and synthesis of multiple peptides, at least two of which (peptides I and III) are encompassed by the claims of the '333 patent. The authors of Kyle were affiliated with Nova Pharmaceutical Corporation. On information and belief, Nova Pharmaceutical Corporation was actively pursuing bradykinin peptides, including the peptides claimed in the '333 patent, during the Plaintiffs' period of delay.

ANSWER: Denied.

19. On information and belief, but for the manipulation of the patent system by the Plaintiffs, the '333 patent would be expired.

ANSWER: Denied.

20. U.S. Patent 5,597,803 (the "'803 patent") is an earlier-expiring, commonly owned and invented patent relating to the same compounds claimed in the '333 patent.

ANSWER: Plaintiffs admit that Sanofi-Aventis Deutschland GmbH is the owner of the expired '803 patent. The named inventors of the '803 patent are Gerhard Breipohl, Stephan Henke, Jochen Knolle, Bernward Schölkens, Hans-Georg Alpermann, Hermann Gerhards, and Klaus Wirth. Plaintiffs deny the remaining allegations of Paragraph 20.

21. The '803 patent issued on January 28, 1997 from U.S. Application No. 373,464, filed on January 17, 1995, which was a continuation of an application filed on April 1, 1993. Ultimately, the '803 patent claims priority to a German patent application, No. 42 11 406.3, filed on April 4, 1992.

ANSWER: Admitted.

22. The '333 patent and its asserted claims relate to a genus of peptide compounds that include the specific compound icatibant. The '803 patent relates to a small genus of compounds that includes a simple analog of icatibant.

ANSWER: Denied.

23. Of the '803 patent's seven listed inventors, five are shared with the listed inventors of the '333 patent. The '803 patent shared an assignee with the '333 patent.

ANSWER: Plaintiffs admit the '803 patent lists Gerhard Breipohl, Stephan Henke, Jochen Knolle, Bernward Schölkens, Hans-Georg Alpermann, Hermann Gerhards, and Klaus Wirth as inventors. Plaintiffs admit that the '333 patent lists Stephan Henke, Hiristo Anagnostopulos, Gerhard Breipohl, Jochen Knolle, Jens Stechl, Berward Schölkens, Hans-

Wolfram Fehlhaber, Hermann Gerhards, and Franz Hock as inventors. Plaintiffs admit that both the '803 and '333 patents were originally assigned to Hoechst Aktiengesellschaft. Plaintiffs deny the remaining allegations of Paragraph 23.

24. Due to Plaintiffs' failure to diligently prosecute the '333 patent, the '803 patent—filed over 3 years after the '333 patent—issued several months before the '333 patent. The '803 patent expired on January 28, 2014, whereas the '333 patent does not expire until July 15, 2019.

ANSWER: Plaintiffs admit that the '803 patent issued from USSN 373,464 ("the '464 application"), which was filed on January 17, 1995. Plaintiffs admit that the '333 patent issued from the '442 application, which was filed on June 7, 1995. Plaintiffs admit that the '803 patent expired on January 28, 2014, and that the current date of expiry of the '333 patent is July 15, 2019. Plaintiffs deny the remaining allegations of Paragraph 24.

25. The '803 patent was co-pending during its entire prosecution (from April 1, 1993 to January 28, 1997) with the applications leading to the '333 patent (from June 30, 1989 to July 15, 1997). However, despite the fact that the '803 patent and the '333 patent were prosecuted simultaneously before different examiners by the same outside prosecution counsel, the '803 patent was never disclosed during prosecution of the '333 patent.

ANSWER: Plaintiffs admit that the '803 patent issued on January 28, 1997 as the result of continuation or continuation-in-part applications dating back to April 1, 1993. Plaintiffs admit that the '333 patent issued on July 15, 1997 as a result of continuation or continuation-in-part applications dating back to June 30, 1989. Plaintiffs admit that the "Attorney, Agent, or Firm" listed on the face of each of the '803 and '333 patents is the law firm Finnegan, Henderson, Farabow, Garrett & Dunner, LLP. Plaintiffs admit that the Primary Examiner listed on the face of the '803 patent is Avis M. Davenpoty. Plaintiffs admit that the Primary Examiner listed on the face of the '333 patent is Cicilia J. Tsang, and that the Assistant Examiner listed on the face of the '333 patent is P. Lynn Touzeau. Plaintiffs admit that the '803 patent was not listed on an IDS in the prosecution of the '333 patent. Plaintiffs further answer that there was no need to list

the ’803 patent on an IDS in the prosecution of the ’333 patent. Plaintiffs deny the remaining allegations of Paragraph 25.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’333 Patent)

26. Fresenius restates and incorporates herein by reference each of paragraphs 1-25 of its counterclaims.

ANSWER: Plaintiffs repeat and incorporate by reference their answer to Paragraphs 1-25 of Defendant’s Counterclaims.

27. The claims of the ’333 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or are invalid under the doctrine of obviousness-type double patenting.

ANSWER: Denied.

28. Specifically, the subject matter in the ’333 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the ’333 patent and the subject matter claimed in the ’803 patent, an earlier-expiring patent with common ownership and inventorship, would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

ANSWER: Denied.

29. Because of the immediate and justiciable controversy between Fresenius and Counterclaim-Defendants, a declaration is necessary and appropriate that the claims of the ’333 patent are invalid under one more of the provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting.

ANSWER: Denied.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-Infringement)

30. Fresenius restates and incorporates herein by reference each of paragraphs 1-29 of its counterclaims.

ANSWER: Plaintiffs repeat and incorporate by reference their answer to Paragraphs 1-29 of Defendant’s Counterclaims.

31. Fresenius has not infringed directly or indirectly any valid claim of the ’333 patent by submitting ANDA No. 208317 to FDA, and the manufacture, use, offer for sale, sale in

the United States, and/or importation into the United States, of the Fresenius Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '333 patent.

ANSWER: Denied. Plaintiffs further answer that "[t]he parties agree that the Stipulation of Infringement and Order (D.I. 75) applies in the same way to Fresenius's December 15, 2017 Amended Answer and Counterclaim (D.I. 93) as it did to Fresenius's January 13, 2016 Answer (D.I. 11) and Fresenius's Amended Answer and Counterclaim (D.I. 41). As such, the parties stipulate that Fresenius's non-infringement counterclaim pleaded in D.I. 93 is dismissed with prejudice." D.I. 94 at ¶ 23.

32. Because of the immediate and justiciable controversy between Fresenius and Counterclaim-Defendants, a declaration is necessary and appropriate that Fresenius has not infringed, directly or indirectly, any valid claim of the '333 patent by the submission of ANDA No. 208317 to FDA, and that the manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of the Fresenius Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '333 patent.

ANSWER: Denied. Plaintiffs further answer that "[t]he parties agree that the Stipulation of Infringement and Order (D.I. 75) applies in the same way to Fresenius's December 15, 2017 Amended Answer and Counterclaim (D.I. 93) as it did to Fresenius's January 13, 2016 Answer (D.I. 11) and Fresenius's Amended Answer and Counterclaim (D.I. 41). As such, the parties stipulate that Fresenius's non-infringement counterclaim pleaded in D.I. 93 is dismissed with prejudice." D.I. 94 at ¶ 23.

THIRD COUNTERCLAIM
(Declaratory Judgment of Unenforceability of '333 patent)

33. Fresenius restates and incorporates herein by reference each of paragraphs 1-32 of its counterclaims.

ANSWER: Plaintiffs repeat and incorporate by reference their answer to Paragraphs 1-32 of Defendant's Counterclaims.

34. The applicants of the '333 patent engaged in a pattern of repetitive re-filings without any effort to advance prosecution of the claimed subject matter, which constitutes an unexplained and unjustifiable delay in prosecution.

ANSWER: Denied.

35. The Plaintiffs failed to advance prosecution of the subject matter claimed in the '333 patent in order to delay issuance of claims encompassing icatibant for as long as possible so as to obtain an extension of their monopoly of the claimed subject matter.

ANSWER: Denied.

36. The Plaintiffs' unreasonable and unexplained delay to advance prosecution of the subject matter claimed in the '333 patent constitutes an egregious misuse of the statutory patent system under the totality of the circumstances.

ANSWER: Denied.

37. Intervening rights required to establish an unreasonable and unexplained delay in prosecution existed during the period of the Plaintiffs' delay, including, but not limited to, Nova Pharmaceutical Corporation's investment in the subject matter of the claims of the '333 patent.

ANSWER: Denied.

38. One or more claims of the '333 patent are unenforceable under the doctrine of prosecution laches.

ANSWER: Denied.

39. To resolve the legal and factual questions raised by Counterclaim Defendants and to afford relief from the uncertainty and controversy that Counterclaim Defendants' accusations have precipitated, Fresenius is entitled to a declaratory judgment that the '333 patent is unenforceable under the doctrine of prosecution laches.

ANSWER: Denied.

RESPONSE TO DEFENDANT'S PRAYER FOR RELIEF

Plaintiffs deny that Defendant is entitled to any relief requested in its Counterclaims, request that the Counterclaims be dismissed with prejudice, and request such other and further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES TO DEFENDANT'S COUNTERCLAIMS

1. Defendant's Counterclaims are barred, in whole or in part, because they fail to state a claim upon which relief may be granted.

2. The '333 patent is valid and enforceable.

3. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 208317 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Fresenius Kabi's ANDA Product—a product (1) that is claimed in the '333 patent and (2) whose use is claimed in the '333 patent—before the expiration of the '333 patent, was an act of infringement of the '333 patent by Defendant.

4. Pursuant to 35 U.S.C. § 271(a), (b), and (c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Fresenius Kabi's ANDA Product before the expiration of the '333 patent will constitute an act of direct infringement and/or indirect infringement, including by inducement and/or contributory infringement of the '333 patent, by Defendant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment in favor of Plaintiffs with respect to Defendant's Counterclaims;

B. A Judgment that Defendant is not entitled to any of the relief requested in its Counterclaims and dismissal of Defendant's Counterclaims with prejudice;

C. An Order granting Plaintiffs the relief sought in Plaintiffs' Complaint;

D. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), the effective date of any approval of Fresenius Kabi's ANDA Product shall be no earlier than the date on which the '333 patent expires, including any regulatory extensions;

E. Injunctive relief pursuant to 35 U.S.C. §§ 271(e)(4)(B) precluding Fresenius Kabi from manufacturing, using selling, offering to sell, or importing Fresenius Kabi's ANDA Product prior to the date on which the '333 patent has expired, including any regulatory extensions;

F. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys' fees;

G. A Judgment awarding Plaintiffs their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

H. Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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January 5, 2018

CERTIFICATE OF SERVICE

I hereby certify that on January 5, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 5, 2018, upon the following in the manner indicated:

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